UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION **THIS DOCUMENT RELATES TO:** **All Direct Purchaser Actions**	**Case No. 1:15-cv-07488-CM-RWL**

PLAINTIFFS' OPPOSITION TO FOREST'S MOTION *IN LIMINE* NO. 10 SEEKING TO EXCLUDE EVIDENCE AND ARGUMENT REGARDING THE POST-AGREEMENT SUBSEQUENT SALES HISTORY OF THE LEXAPRO AUTHORIZED GENERIC

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I. INTRODUCTION

Plaintiffs submit this opposition to Forest's Motion in *Limine* No. 10 (ECF No. 781) which seeks to exclude evidence that Forest and Mylan made $**0.00 profits** in the second year of authorized generic Lexapro sales rather than the **$79.3 million** Forest had projected. This is important because Forest's defense is based on trying to justify the **$32.5** million it paid Mylan to amend the original Lexapro Agreement as something other than a reverse payment to induce Mylan to drop its patent challenge. Specifically, the Lexapro Amendment extended the minimum term of the Original Lexapro Agreement by one year. Forest claims that based on its projections at the time of the Namenda patent settlement and the Lexapro Amendment, it reasonably believed that the monies it paid to Mylan ($20 million upfront and $12.5 million in reduced first-year royalties) would be made up in that second year, making the Lexapro Amendment cost neutral (under the Lexapro Amendment, the $79.3 million in alleged projected profits for the second year would be split 60-40 between Mylan and Forest such that Forest's second year profit share was forecasted to be roughly $32 million). Of course, if the forecasts were so grossly inflated to an unrealistic degree – as the actual outcomes and Mylan's contemporaneous forecasts reflect – Forest's justifications for its $32.5 million payment fall apart.

As will be shown below, evidence of actual outcomes, and their foreseeability, are factors for the jury to consider in determining the reliability of the forecasts Forest's witnesses claim justify the Lexapro Amendment and the assumptions that drove them. As the case law demonstrates, in assessing the reasonableness of forecasts, a dramatic departure from the actual outcome may be evidence of their unreliability. *Union Bank of Switz. v. Deutsche Fin. Servs. Corp.*, 98 Civ. 3251 (HB), 2000 U.S. Dist. LEXIS 1481, at *28 (S.D.N.Y. Feb. 14, 2000) ("the court may consider information originating subsequent to the [valuation] date if it tends to shed

light on a fair and accurate assessment of the asset or liability as of the pertinent date.") (alteration in original).

The key issue therefore is whether the actual results as to second year profits were foreseeable in March 2010 as Plaintiffs' expert Dr. Ernest Berndt opines or were unexpected as Forest's expert Phillip Green opines. Where forecasts depart so markedly from the actual results, as was the case here, the reasons why are clearly probative of the reasonableness of the forecasts. Here the parties will present their competing experts whose reports and deposition testimony sparred over this very issue. How the jury resolves this battle of the experts may very well be determinative as to their ultimate finding as to whether Forest made a large payment to Mylan.

Significantly, Forest's expert, Philip Green, opined that there were unforeseeable events that account for the difference between the forecasts and the actual results. Declaration of Joseph Opper ("Opper Decl.") Ex. 24, Green Rpt. at ¶ 67. As set forth *infra*, Plaintiffs' expert, Prof. Berndt, analyzed the forecasts' various assumptions against the actual results, and testified in detail as to the foreseeability of the actual outcomes based on previous similar generic product launches and market conditions. Now Forest, after initially introducing the actual outcomes as a benchmark, performs an about face and seeks to exclude this critical evidence to prevent the jury from assessing the reliability of the forecasts and the credibility of the experts. As will be shown *infra*, in evaluating forecasts, courts routinely compare them to the actuals, particularly when the differences are vast, and the explanation is implausible or insufficient. The almost $80 million gap between the actual outcomes and Forest's forecasts are clearly probative of whether Mr. Green's valuation opinion is plausible. Prof. Berndt opines that it is not. Ultimately it is for the jury to decide.

Plaintiffs do not dispute that under *Actavis* and the Rule of Reason, "the reasonableness of an agreement is to be assessed at the time the agreement was made." Defs.' Br. at 1 (although Forest conflates its Lexapro forecasts with the challenged agreement) (ECF No. 782). Forest's reliance on *Valley Drug Co. v. Geneva Pharm.*, 344 F.3d 1294, 1306 (11th Cir. 2003), however, is misplaced. In *Valley Drug*, a pre-*Actavis* case, the court explained that a post-settlement finding of patent invalidity could not be determinative of whether that patent settlement was unreasonable when made. 344 F.3d at 1306. *Valley Drug* did not address whether subsequent events could be probative of whether a proffered defense was reasonable, but the very language Forest quotes makes clear that reasonableness is subject to scrutiny. Defs.' Br. at 2, quoting *Valley Drug*, 344 F.3d at 1306 ("[T]he *reasonableness* of agreements under the antitrust laws are to be judged at the time . . .") (emphasis added). And there is nothing in *Actavis* or the rules of evidence to remotely suggest that where the plaintiff presents evidence that the defendant's rationale for the payment was contrived or unreasonable, post-agreement evidence is not relevant to the question of whether the defendant's explanation is credible or merely a cover to conceal a reverse payment. In fact, *Actavis* invites such an assessment by offering a potential defense for "fair value for services" and explaining that "[a]n antitrust defendant may show . . . that *legitimate* justifications are present." *FTC v. Actavis, Inc.*, 570 U.S. 136, 156 (2013) (emphases added). The cases dealing with the reasonableness of valuations routinely consider actual results.

The issue here is not whether Forest is just bad at forecasting, but whether its profit projections in this case were knowingly and deliberately inflated for an anticompetitive purpose.

II. ARGUMENT

A. Background

On July 21, 2010, the same day Forest and Mylan settled the Namenda IR patent litigation, Forest agreed to pay Mylan $32.5 million in connection with the Lexapro Amendment. Pls.' Contentions, ECF No. 699-1 at ¶ 127. Pursuant to the Lexapro Amendment, Forest paid Mylan $20 million upfront and reduced the royalties Mylan would owe Forest for the first $150 million of Mylan's Lexapro AG sales by $12.5 million. *Id*. at ¶ 129. Plaintiffs contend the $32.5 million was a reverse payment to induce Mylan to settle the patent litigation suit and delay marketing a generic version of Namenda until July 11, 2015. Forest contends the $32.5 million was "fair value" necessary to get Mylan to agree to stay in the deal for a second year during which time Forest would continue to share in Mylan's authorized generic profits. *Id*. at ¶¶ 147-52. Forest's "fair value" defense is based exclusively on forecasts that were first generated on or after March 15, 2010, the same day Forest and Mylan reached an agreement in principle to settle the Namenda patent case. *Id*. at ¶ 149. These "second year" forecasts purport to show that Mylan would generate over **$79.3 million** in total second year generic profits when the actual total second year profits were **$0.00**. Forest misleadingly suggests that the gap between the actual and projected profits was only about $20 million (Defs.' Br. at 1) when in fact the difference was almost four times greater. Forest projected $79.3 million (not $20 million) in total pre-split second year profits: Forest was entitled to a 40% profit share, or $31.7 million, of which it was then obligated to pay one-third to its manufacturing partner, Lundbeck, leaving Forest with approximately $21.1 million. Opper Decl. Ex. 24, Green Rpt. Ex. C-1 p .2. But Mylan itself contemporaneously forecasted only $5.2 million in total second year pre-split profits (Ex.25, PX-0243 at MYLMEMA_003601) – of which Forest would get $2.08 million post-split.

Moreover, prior to the March 15, 2010 forecasts, there is simply zero contemporaneous evidence that Mylan intended to terminate the Lexapro Agreement after only one year. Pls.' Contentions, ECF No. 699-1 at ¶ 152.

There are numerous disabling flaws with Forest's second-year forecasts and Mr. Green's analysis of them (Plaintiffs did not challenge Mr. Green on *Daubert* grounds and instead intend to challenge his opinions through cross-examination at trial). Mr. Green uncritically accepted numerous assumptions underlying the forecasts, such as the share of the generic market Mylan would retain during the first six months of generic sales and thereafter. During the first six months Mylan would be competing against Teva, the largest generic company. Thereafter, up to 12 additional generic competitors would enter the market, all eroding Mylan's market share. *Id*. at ¶¶ 151-52. Plaintiffs' expert Dr. Berndt reviewed the same *pre-settlement* evidence but concluded that the March 2010 Lexapro forecasts "are based on unreasonable and implausible assumptions" and that "[k]nowledgeable industry observers would plausibly have expected that during the 180 day exclusivity period, price competition between Mylan and the generic titan Teva would be very intense, particularly when First Filer Teva had long been aware that Mylan would have a two week launch advantage that Teva would need to overcome competitively." Opper Decl. Ex. 7, Am. Reply Expert Rep. of Ernst R. Berndt, Ph.D. ("Berndt Reply"), Nov. 8, 2017 at ¶ 38. And as to the reasonableness of Forest's pre-settlement forecasts for the period after six months (including the second year), Dr. Berndt opined:

> In conducting . . . an analysis of *expected* sales, volume, pricing and market share for generic competition, perhaps the most critical input is the *expected* identity (i.e., whether Mylan's competitor, here Teva, is a fierce competitor), entry timing and number of generic competitors. The more competitors that are *anticipated*, other things equal, the lower the *expected* pricing would be (at least to a certain point), and the lower volume that each competitor would expect to attain or maintain. There is a clear body of literature that shows that as the number of

> competitors increase, other things equal, the average generic price of the molecule falls, as does the average generic market share.

Id. at ¶ 37 (emphases added).

Significantly Mr. Green considered it necessary to affirmatively raise and attempt to explain away the very market results that Forest's now seeks to exclude: that total second year profits were **$0.00** and not the **$79.3 million** Forest had projected. Mr. Green attributes the discrepancy to "higher-than-anticipated discounting by generic competitors." Opper Decl. Ex. 24, Green Rpt. ¶ 67. Dr. Berndt agreed that the actual sales results were relevant but came to a different conclusion as to why:

> Given that Teva and Mylan were competing during what would otherwise have been Teva's sole exclusivity period, and the two-week advance launch window that Mylan had, both of which were known by the market for more than two years prior to generic launch, it would have been irrational for purchasers such as the wholesalers and large pharmacy chains to enter into long-term contracts with either of these competitors unless the contracts permitted all sorts of adjustments as actual generic molecule prices decreased. Indeed, with two years advance notice of Mylan's two week head start, Teva would have been expected to be very aggressive in trying to diminish Mylan's advantage by competing for such purchases to ensure as much recognition of the First Filer opportunity as possible.

Opper Decl. Ex. 7, Berndt Reply Rpt. at ¶ 41. *See id*. at ¶ 39 (the actual outcome "would have been the only reasonably foreseeable projection for a competent industry analyst who was aware of the number of generic entities with Tentative Approval as of January 2010," and that as a result "it would have been unreasonable for Forest to have relied upon the projections that Mr. Green cites."). These differing opinions will necessarily lead to a battle of the experts that the jury must decide but where, as here, Plaintiffs have raised a plausible claim that the forecasts were designed to conceal a reverse payment, the actual market results will "shed light" on the propriety of the forecasts and should be considered by the jury.

B. Post-Agreement Evidence That Actual Second Year Generic Lexapro Profits Were $0.00 Is Relevant to the Question Whether Forest's Profit Projections of over $79 Million Were Implausible and Grossly Unrealistic

Contrary to Forest's argument, evidence of the actual profits earned from the second year sales of generic Lexapro is relevant to Plaintiffs' claim that Forest's profit forecasts were implausible and grossly unrealistic, designed to conceal a reverse payment. Courts in multiple valuation contexts have recognized that *ex post* evidence is probative of the objective reasonableness of a projection or valuation. In order to assure that valuations are "based in reality, the court may consider information originating subsequent to the [valuation] date if it tends to shed light on a fair and accurate assessment of the asset or liability as of the pertinent date." *Union Bank of Switz.*, 2000 U.S. Dist. LEXIS 1481, at *28 (alteration in original) (internal quotations omitted); *Saltzman v. C.I.R.*, 131 F.3d 87, 92-93 (2d Cir. 1997) ("subsequent events are not considered in fixing fair market value [for tax purposes] *except to the extent that they were reasonably foreseeable on the date of the gift*.") (alteration and emphasis added.); *MFS/Sun Life Tr.-High Yield Series v. Van Dusen Airport Servs. Co.*, 910 F. Supp. 913, 944 (S.D.N.Y. 1995) ("We know, with hindsight, that the forecasts were not realized. But the question the court must decide is *not* whether [the] projection was correct, for it clearly was not, but whether it was reasonable and prudent when made. Because projections tend to be optimistic, their reasonableness must be tested by an objective standard anchored in the company's actual performance.") (alteration and emphasis in original) (internal citations and quotation marks omitted.); *Coated Sales, Inc. v. First E. Bank, N.A.*, 144 B.R. 663, 668 (Bankr. S.D.N.Y. 1992) ("the court may consider information originating subsequent to the transfer date if it tends to shed light on a fair and accurate assessment of the asset or liability as of the pertinent date . . . This assures that the valuation is based in reality.")(internal citations and

quotation marks omitted.); *Krapf v. United States*, 977 F.2d 1454, 1459-60 (Fed. Cir. 1992) ("We conclude that the case law respecting evidence of events after a gift cannot be extrapolated into an exclusionary rule with two exceptions . . . More appropriately, the stated exceptions, namely, where there is no material change in the corporation between donation and subsequent sale ***or where the changes would be foreseeable***, simply illustrate two situations when post-transaction evidence should be considered.") (Emphasis added); *cf. E.M. v. Pajaro Valley Unified Sch. Dist. Office of Admin. Hearings*, 652 F.3d 999, 1004-05 (9th Cir. 2011) ("after-acquired evidence may shed light on the objective reasonableness of a school district's actions at the time the school district rendered its decision.") (Internal quotation marks omitted.).

As previously noted, Forest's reliance on *Valley Drug* for the proposition that subsequent events cannot be relevant to what an antitrust defendant knew or intended at the time it entered the challenged agreement is misplaced. To the contrary, the court explicitly noted that it "was not called upon to decide what the antitrust consequences of such circumstances [subsequent events] might be." *Valley Drug*, 344 F.3d at 1306, n.19.

Finally, Forest's refers to an out-of-context snippet from Plaintiffs' expert Prof. Einer Elhauge's deposition for the apparent proposition that the reliability of the assumptions underlying a forward-looking financial statement can never be questioned. Defs.' Br. at 2. But Prof. Elhauge was referring to an internal Mylan 5 Year Financial Plan regarding generic Namenda IR, not generic Lexapro, that was generated after the Namenda settlement agreement had been finalized and about which there was no suggestion or claim that the assumptions underlying the analysis were implausible, grossly unrealistic or contrived.

III. CONCLUSION

For the foregoing reasons, Forest's Motion *in Limine* No. 10 to Exclude Evidence and Argument Regarding the Post-Agreement Subsequent Sales History of the Lexapro Authorized Generic should be denied.

Dated: June 14, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2019, I electronically filed the above by CM/ECF system.

Respectfully submitted,

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